EXHIBIT 96

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836 | http://www.pharmacy.ohio.gov

License 010000650

Prescription Supply, Inc.

2233 Tracy Road
Northwood, OH 43619
Wood County

Wholesaler - Category 3

Non-Pharmacy Inspection

June 6, 2018

License 010000650 - Prescription Supply, Inc.

Full

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836
http://www.pharmacy.ohio.gov

Completed by David Gonzalez
Start 6/6/2018 1:30 PM
End 6/6/2018 3:45 PM

Organization

Name
Prescription Supply, Inc.

License Type
Wholesaler - Category 3

Category

License Number
010000650

Business Type
FS - Full Service

DEA Number
344454964

Responsible Person
Thomas G Schoen

Hours of Operation
M-F 9am-6 pm

Contact

Address
2233 Tracy Road
Northwood, OH 43619
Wood County

Primary Number
(419) 661-6600

Fax Number
(419) 661-6617

Website

Personnel

Name	Initials	Position	I.D. No.	Phone	Email
James T. Schoen		Manager		(419) 661-6600 x ext138	jschoen@prescriptionsupply.com
Thomas G Schoen		Responsible Person			

1) Initial Inspection Information

1) Personnel Conducting Inspection

Observation
The following inspection was conducted in conjunction with: Agent Gonzalez reference case 2017-1528

2) Were multiple inspection guides used during this inspection?

No

3) Facility Description

Observation
This inspection is of Prescription Supply Inc. an independent wholesaler.

2) Licensing

1) Is the license current, signed, and on-site available for viewing at the time of inspection?

Yes

2) The responsible person on the license is correct, and appropriate for the licensed location.

Yes

3) The facility has a current DEA certificate.

Yes

Observation
DEA expiration is 3/31/2019

3) Security

1) Dangerous drugs are stored in a secure area with access by authorized personnel only?

Yes

Observation
This is a wholesale warehouse. All dangerous drugs are secure and appear to be tamper evident. Controlled substances are stored in a secure "vault" area located within the warehouse.

3) Adequate systems are in place to detect and deter drug diversion and to prevent unauthorized access to drug stock.

Yes

Observation
The entire management team has access to the building.

4) Minimum Standards/Cleanliness

1) The facility was observed clean, well-lighted, well-ventilated and in an orderly condition for the storage of drugs and devices.

Yes

Observation
The drug stock and records of accountability are store in a clean, and organized manner.

6) References

1) The licensee is able to access current federal and state drug laws and rules.

Yes

Observation
Both paper and online reference are available at this location.

8) Drug Purchases

2) The licensee has a policy/procedure in place to verify the TDDD/WDDD of the distributor/wholesaler prior to purchsing dangerous drugs or controlled substances from them.

Yes

Observation
A license verification policy and procedure is in place at this location.

19) Drug Records and Inventories

1) The facility maintains all drug records on-site for a period of three years.

Yes

Observation
This facility maintains all records of accountability for a period of three years.
(OAC 4729-9-22) Each prescriber or terminal distributor of dangerous drugs shall keep a record of all dangerous drugs received, administered, dispensed, distributed, sold, destroyed, or used. The acts of prescribing, administering, dispensing, and destroying of a dangerous drug must be documented with the positive identification of the responsible individual pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code. These records may be kept electronically if the method is approved by the state board of pharmacy and the records are backed-up each business day.
(A) Records of receipt shall contain a description of all dangerous drugs received, the kind and quantity of dangerous drugs received, the name and address of the persons from whom received, and the date of receipt.
(B) Records of administering, dispensing, or using dangerous drugs shall contain a description of the kind and quantity of the dangerous drugs administered, dispensed, sold, or used, the date, the name and address of the person to whom or for whose use, or the owner and identification of the animal for which, the dangerous drug was administered, dispensed, or used.
(C) Records of dangerous drug destructions, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed, the date destroyed, the method of destruction, the positive identification of the prescriber or responsible person that performed the destruction, and if used the positive identification of the person that witnessed the destruction.
(D) Records of dangerous drugs, other than controlled substances, administered, dispensed, or used which become a permanent part of the patient's medical record shall be deemed to meet the requirements of paragraph (B) of this rule.
(E) All records of receipt, distribution, administering, dispensing, selling, destroying, or using dangerous drugs shall be kept for a period of three years at the place where the dangerous drugs are located and upon request provided to a state board of pharmacy officer, agent, and/or inspector within three working days, excluding weekends and holidays. Any terminal distributor of dangerous drugs intending to maintain such records at a location other than this place must first send a written request to the state board of pharmacy. The request shall contain the terminal distributor of dangerous drug name and license number of the requestor and the name and address of the alternate location. The state board of pharmacy will send written notification to the terminal distributor of dangerous drugs documenting the approval or denial of the request. A copy of the board's approval shall be maintained with the other records of dangerous drugs. Any such alternate location shall be secured and accessible only to representatives of the terminal distributor of dangerous drugs.

4) The facility maintains an annual inventory of controlled substances in accordance with OAC 4729-9-14.

Yes

Observation
Prescription Supply conducts a monthly inventory of all of it's controlled substances. The last monthly inventory was conducted on June 1, 2018.

5) The facility maintains records of controlled substances received, administered, dispensed or used other than by prescription separately from all other records of the registrant, and in a readily retrievable format.

Yes

6) The facility conducts routine audits of controlled substances on-hand.

Yes

7) Theft or loss of dangerous drugs, controlled substances and/or drug documents has been reported to the Ohio State Board of Pharmacy.

Yes

Observation
Any theft or loss of dangerous drugs must be reported by law to the Ohio State Board of Pharmacy and local law enforcement immediately upon discovery. Notify the DEA if controlled substances were involved.

Theft or loss must be reported verbally to the Ohio State Board of Pharmacy (614-466-4143) or a local Pharmacy Board Employee immediately upon discovery and in writing to the Ohio State Board of Pharmacy (dea106reporting@pharmacy.ohio.gov) within 30 days of the discovery of the theft or loss.

8) The following records have been requested by the Ohio State Board of Pharmacy.

Observation
(OAC 4729-5-29)
(C) Records relating to the practice of pharmacy, the administration of drugs, or any patient specific drug transaction which may be required as evidence of a violation shall be released to a member, inspector, agent, or investigator of the state board of pharmacy or any state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug upon his request. Such person shall furnish a receipt to the person having legal custody of the records. If the record is a prescription, the receipt shall list the following information:
(1) Prescription identification number; or, if an order for medication, the name of the patient;
(2) The drugs prescribed;
(3) Quantity of drugs prescribed and dispensed;
(4) Name of the prescriber;
(5) Date, name of agency, and signature of person removing the records.
(D) All such records, including consents, memoranda of emergency disclosures, and written requests pursuant to paragraph (A)(9) of this rule, shall be kept on file at the pharmacy for a period of three years in a readily retrievable manner.
(OAC 4729-9-22) Each prescriber or terminal distributor of dangerous drugs shall keep a record of all dangerous drugs received, administered, dispensed, distributed, sold, destroyed, or used. The acts of prescribing, administering, dispensing, and destroying of a dangerous drug must be documented with the positive identification of the responsible individual pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code. These records may be kept electronically if the method is approved by the state board of pharmacy and the records are backed-up each business day.
(E) All records of receipt, distribution, administering, dispensing, selling, destroying, or using dangerous drugs shall be kept for a period of three years at the place where the dangerous drugs are located and upon request provided to a state board of pharmacy officer, agent, and/or inspector within three working days, excluding weekends and holidays. Any terminal distributor of dangerous drugs intending to maintain such records at a location other than this place must first send a written request to the state board of pharmacy. The request shall contain the terminal distributor of dangerous drug name and license number of the requestor and the name and address of the alternate location. The state board of pharmacy will send written notification to the terminal distributor of dangerous drugs documenting the approval or denial of the request. A copy of the board's approval shall be maintained with the other records of dangerous drugs. Any such alternate location shall be secured and accessible only to representatives of the terminal distributor of dangerous drugs.

20) Adulterated/Expired Drugs

1) The facility has a policy/procedure to regularly check drug stock for expired/adulterated products and to remove them from stock areas.

Yes

Observation
Expired or adulterated drugs are checked during the monthly inventory, as well as every three months.

2) Adulterated/expired drugs are stored in a separate and secure area apart from the storage of drugs used for dispensing and administration.

Yes

Observation
Expired and / or adulterated drugs are segregated from the active drug stock.

3) In a facility licensed as a terminal distributor of dangerous drugs, adulterated/expired drugs are stored no longer than 1 year from the date of adulteration/expiration.

Yes

23) Wholesale Facilities

1) The facility is of suitable size and construction to facilitate cleaning, maintenance and proper operations.

Yes

2) The facility maintains a quarantine area for adulterated drugs.

Yes

Observation
This is called the morgue area.

3) The facility is secure from unauthorized entry.

Yes

4) The facility is equipped with an alarm system to detect unauthorized entry after hours.

Yes

5) Dangerous drugs are stored at appropriate temperatures.

Yes

6) Shipping containers are visually examined to prevent the acceptance or delivery of contaminated dangerous drugs.

Yes

Observation

(OAC 4729-9-16) The following minimum requirements shall apply to all persons distributing dangerous drugs at wholesale in Ohio :

(F) All shipments of dangerous drugs shall be examined in accordance with the following:
(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents;
(2) Each outgoing shipment shall be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions;
(3) The recordkeeping requirements in paragraph (H) of this rule shall be followed for all incoming and outgoing dangerous drugs.

8) The wholesaler obtains certificates from licensed terminal distributors of dangerous drugs prior to a sale being made.

Yes

9) The facility has a system in place to identify and report suspicious orders for drugs to the Ohio State Board of Pharmacy. Warning

Yes

Observation

On October 20, 2017 the State of Ohio Board of Pharmacy submitted an inspection report to Prescription Supply Inc. highlighting a few observations based off an initial inspection performed on May 22, 2017 by BOP Agents. A response was received by Prescription Supply Inc. answering the observations made to the inspection report dated 10/20/2017.
One of the observations was reference a spike in sales of Oxycodone 30 mg to Medicine Shoppe, Bellevue, Ohio DEA# BT2914960 for January 2015. Prescription Supply replied stating that this was not reported as suspicious because Medicine Shoppe advised their main supplier (Cardinal Health) said there was a drug shortage and backorder of this particular drug. Per James Schoen, their controlled substance manager, Prescription Supply faxed an "Increased Purchase Request" form to Medicine Shoppe asking them to complete and return, explaining the reason for the extra sales. This form was attached to Prescription Supply's original response, and was signed by Medicine Shoppe Pharmacist Amy Schwan.
The second observation was reference a spike in sales for Oxycodone 30 mg in April 2014 to Shaffer Pharmacy, Toledo, Ohio DEA# AS8550243. Prescription Supply replied in a similar fashion, and faxed a "Increase Purchase Request" form to Shaffer Pharmacy. Pharmacist Tom Tadsen returned this completed form to Prescription Supply stating that two new Physicians opened up practice in the same building as Shaffer Pharmacy, thus increasing sales. These two Doctors were listed on the form by Tasden as Dr. James Otting and Dr. Amar Goyal. This form was also signed by Tom Tasden of Shaffer Pharmacy. According to Control Substance Manager James Schoen, he called and spoke directly with both Pharmacists from Medicine Shoppe and Shaffer Pharmacy. He advised that both reiterated the same explanations as what was documented on the Increase Purchase Request form. No other supporting documentation was received from either pharmacy. Agent Gonzalez also asked Mr. Schoen what the policy is for when a purchase request comes in that is over their threshold? Mr. Schoen replied as saying, Prescription Supply will call and speak with the Pharmacy making the request, and also compare their request with their original pharmacy questionnaire as it pertains to their manner of dispensing. Once all of this is completed, a determination is made on whether to make the sale(s).

Corrective Action

Agent Gonzalez advised Prescription Supply Inc. that in the future, additional supporting documentation may be beneficial to accompany their Increase Purchase Request form.

(OAC 4729-9-16) The following minimum requirements shall apply to all persons distributing dangerous drugs at wholesale in Ohio :

(H) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of dangerous drugs.
(1) These records shall include but not be limited to the following information:
(e) A system of procedures shall be designed and operated to disclose orders for controlled substances and other dangerous drugs subject to abuse.
(i) The wholesaler shall inform the state board of pharmacy of suspicious orders for drugs, as described in paragraph (H)(1)(e) of this rule, when discovered. Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns.
(ii) Reports, generated by the system as described in paragraph (H)(1)(e) of this rule, shall be furnished to the state board of pharmacy within three working days of receipt of a request from the board. The reports shall include the name and address of the purchaser, date of purchases, product trade name, national drug code (NDC) number, size of package, and quantity purchased.

11) The facility maintains written policies and procedures for the receipt, security, storage, inventory and distribution of dangerous drugs.

Yes

14) The wholesaler conducts an inventory of controlled substances in accordance with OAC 4729-9-16 and applicable federal laws.

Yes

Observation

(OAC 4729-9-16) The following minimum requirements shall apply to all persons distributing dangerous drugs at wholesale in Ohio :

(H) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of dangerous drugs.

(2) Inventories and records shall be made available for inspection and photocopying by properly identified and authorized state board of pharmacy designated agents, federal, state, or local law enforcement agency officials for a period of three years following disposition of the drugs.

(I) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following

33) Inspection Affirmation

1) Inspection Affirmation

Observation

As the person in charge, at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent, and understand its content. If this inspection report requires a written response of corrective action, the response shall be provided to the Ohio State Board of Pharmacy within 30 days of this inspection. I understand that if I am not the Responsible Person documented on this site's Ohio TDDD license, I will ensure the Responsible Person is notified of this inspection report and any corrective actions required. Responses can be emailed (with a copy of the inspection report) to writtenresponse@pharmacy.ohio.gov or they may be mailed to 77 South High Street, 17th Floor, Columbus, Ohio 43215.

Summary

Warning

Reviewed by James T. Schoen

(signature)